Maryland
DEPARTMENT OF HEALTH

Lemtrada (alemtuzumab)

Lemtrada is a CD52-directed cytolytic monoclonal antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include relapsing-remitting disease and active secondary progressive disease, in adults.* Because of its safety profile, the use of Lemtrada should generally be reserved for patients who have had an inadequate response to two or more drugs indicated for the treatment of MS.

*Lemtrada is not recommended for use in patients with clinically isolated syndrome (CIS).

- Lemtrada will be considered for coverage when **ALL** of the criteria below are met, confirmed with supporting medical documentation.

I. Criteria for Initial Approval

- Patient must be at least 18 years of age.
- Must be prescribed by a neurologist or a practitioner specializing in the treatment of MS.
- Patient has been diagnosed with a **relapsing form** of multiple sclerosis:
  - Relapsing remitting disease (RRMS), or
  - Secondary progressive MS (SPMS) with relapses.
- MS diagnosis confirmation:
  - Confirmed diagnosis of MS as documented by clinical history and imaging.
- Prescriber and patient must be enrolled in and meet the conditions of the LEMTRADA REMS program.
- Lemtrada must be used as single agent therapy;
- Patient should have had an inadequate response to an adequate trial of two or more drugs indicated for the treatment of MS.
  - Examples include: AVONEX, PLEGRIDY, REBIF, EXTAVIA, COPAXONE, TECFIDERA, GILENYA, AUBAGIO, OCREVUS; and TYSABRI.
- Prior to initiation of Lemtrada the following will be evaluated:
  - Baseline skin exam for melanoma.
  - Patient must not have infection with human immunodeficiency virus.
  - Patient has been evaluated and screened for the presence of varicella zoster virus (VZV) and vaccinated, if required, prior to initiating treatment.

- Patient should be screened for the presence of tuberculosis according to local guidelines.
- Must not be administered concurrently, or within six weeks prior to treatment, with live vaccines.
- Administered with antiviral prophylaxis for herpetic viral infections initiated on the first day of treatment and continued for two months following treatment (or until the CD4+ lymphocyte count is ≥ 200 cells/mcL).
- Patient has a baseline urine protein to creatinine ratio measured prior to initiation of treatment.
- Patient has a baseline thyroid-stimulating hormone (TSH) level prior to initiation of treatment.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy **(in Section I.)** must be met;

AND

The provider attests to a positive clinical response, as demonstrated by:

- Patient tolerating treatment and there continues to be a medical need for the medication.
- Patient has disease stabilization or improvement in disease (as defined by standard parameters for the patient's condition).
- Patent has not received two or more treatment courses.

III. Dosing/Administration

Lemtrada must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- First course: 12 mg/day on 5 consecutive days (60 mg total dose).
- Second course: 12 mg/day on 3 consecutive days (36 mg total dose), administered 12 months after the first treatment course.
- Subsequent courses: 12 mg/day on 3 consecutive days (36 mg total dose) administered, as needed, at least 12 months after the last dose of any prior treatment course.

IV. Length of Authorization for Initial Therapy

Lemtrada will be authorized for 12 months when criteria for initial approval are met. Continuing therapy will be authorized for 12 months.

V. Billing Code/Information

- J0202 - Injection, alemtuzumab, 1 mg; 1mg = 1 billable unit

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 10/29/2020
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